

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

IMPAX LABORATORIES, INC.,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA) INC.  
and CADILA HEALTHCARE LIMITED

Defendants.

Civil Action No. 2:17-13476 (SRC)(CLW)

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**FINDINGS OF FACT, CONCLUSIONS OF  
LAW, AND ORDER GRANTING MOTION  
TO SEAL PURSUANT TO LOCAL RULE 5.3**

THIS MATTER having been brought before the Court by way of Defendants Zydus Pharmaceutical (USA) Inc. and Cadila Healthcare Limited's (collectively, "Defendants") Consolidated Motion to Seal portions of the November 2, 2018 teleconference transcript before the Honorable Cathy L. Waldor, U.S.M.J.; and the Court having considered the parties' submissions and proposed sealed information, and the factors contained in Local Civil Rule 5.3.(c)(2); and Plaintiff not objecting to the relief sought herein; and for other and good cause having been show, the Court hereby finds:

**FINDINGS OF FACT**

1. Through discovery in this case, the parties have produced confidential information, the public disclosure of which would affect legitimate business interests. To protect the confidentiality of this information, the parties agreed to maintain the confidentiality of any materials produced pursuant to the Stipulated Discovery Confidentiality Order ("DCO"), entered by the Honorable Cathy L. Waldor, U.S.M.J. on August 16, 2018 (ECF No. 53).

2. The DCO allows the parties to designate information as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL." The DCO acknowledges that the parties will exchange documents that contain confidential information, and strictly limits access to these documents.

The DCO further provides that any party wishing to file with the Court material designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” must file an Omnibus Motion to Seal pursuant to Local Rule 5.3(c).

3. Pursuant to the DCO, Defendants move to seal the Confidential Materials relating to its proprietary commercial and business interests, including information relevant to its research, development, and technical information because they contain, reference, and/or discuss documents and information designated by Defendants as “HIGHLY CONFIDENTIAL” and/or as “CONFIDENTIAL” in accordance with the DCO.

4. Defendants seek to protect confidential and proprietary information identified in the Appendix to the Declaration of Theodora McCormick in Support of the Motion to Seal pursuant to Local Civil Rule 5.3 (“Defendants’ Confidential Information”);

**Defendants’ Confidential Information:**

5. Defendants’ Confidential Information, all of which is identified in the Appendix to the Declaration of Theodora McCormick, refers to proprietary commercial and business interests, including information relevant to Defendants’ research, development, and technical information on the components and formulation of its ANDA product, which is presently unavailable to the public. The DCO entered in these matters provides for the confidential treatment of this type of proprietary information.

6. Defendants have a legitimate interest in maintaining the confidentiality of this commercially sensitive business information, including research, development, and technical information related to the components and formulation of its ANDA product. Defendants have a legitimate interest in protecting this information as confidential, because their competitors in the marketplace could utilize the information to gain an unfair competitive advantage to their

detriment. Defendants have invested significant resources into the development of its ANDA product with the expectation that documents containing such competitively sensitive and proprietary information would be confidential and remain unavailable to competitors. There is substantial public interest in ensuring that this non-public information relating to Defendants' ANDA product remain confidential and will not become public at a later date.

7. The clearly defined and serious injury that would result should the proposed Order to seal the Confidential Information not be entered is that valuable business and trade secrets created at substantial expense by Defendants will be lost and competitors would unjustly gain access to them. Confidential research information would be revealed to the public and Defendants' competitors, and these competitors would unjustly gain the ability to thwart, anticipate or usurp those plans and strategies to the competitors' advantage and Defendants' loss.

8. There is no less restrictive alternative available other than to seal the unredacted materials containing the confidential information identified in the Appendix to the Declaration of Theodora McCormick, and allowing redacted versions of the transcript be filed and made publicly available.

### **CONCLUSIONS OF LAW**

9. The Court, having considered this matter pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 5.3, and the submissions in support of the Motion, finds that Defendants have satisfied its burden of proving under Local Civil Rule 5.3(c) and applicable case law, that the information sought to sealed by Defendants contains CONFIDENTIAL and/or HIGHLY CONFIDENTIAL information that warrants sealing.

10. Although there exists in civil cases a common law public right of access to judicial proceedings and records, the right of public access is not absolute and the presumption of

public access is rebuttable. *See Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192, 194 (3d Cir. 2001) (citation omitted). The party seeking to seal part of a judicial record bears the burden of demonstrating that “the material is the kind of information that courts will protect.” *Miller v. Indiana Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (quoting *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984)). The Court has power to seal confidential information based on its inherent supervisory authority over its own records and files to deny public access to judicial records where those records might “become a vehicle for improper purposes.” *In re Cendent*, 260 F.3d at 194. Moreover, Fed. R. Civ. P. 26(c)(1)(G) expressly allows the court to protect materials containing “trade secret[s] or other confidential research, development, or commercial information[,]” upon motion by a party, to prevent harm to a litigant’s competitive standing in the marketplace. *See Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 529 F. Supp. 866, 889-91 (E.D. Pa. 1981).

11. The inclusion of trade secrets and other confidential information in documents warrants the sealing of such documents. “A well-settled exception to the right of access is the ‘protection of a party’s interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.’” *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). As such, “[t]he presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure.” *Id.* (citations omitted).

12. The Third Circuit, as well as this Court, has recognized on numerous occasions that confidential and sensitive business information is the type of information that should be protected from public disclosure. *See, e.g., Publicker*, 733 F.3d at 1071 (“protection of a party’s interest in confidential commercial information” is an exception to the right of public access);

*Purdue Pharm. Products v. Actavis Elizabeth*, No. 12-cv-5311, 2015 U.S. Dist. Lexis 111363, at \*2 (D.N.J. Aug. 24, 2015) (sealing part of trial transcript where “revealing the confidential business information to the public and competitors to the parties to this action would injure the parties’ business interests”).

13. In particular, this Court has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, drug master files, formulations, and other confidential testing by drug manufacturers. *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d at 667 (affirming magistrate judge’s denial of motion to unseal documents that contained information relating to defendant’s ANDA, DMF, processes, formulations, and testing); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm. Inc.*, No. 14-4727, 2015 U.S. Dist. LEXIS 103716 at \*6 (D.N.J. Aug. 7, 2015) (granting motion to seal portions of documents containing “highly proprietary business information regarding the development, formulation, manufacture and sale of [Mylan’s] ANDA products”); *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 U.S. Dist. Lexis 212, at \*6-8 (D.N.J. Jan. 3, 2017) (sealing confidential manufacturing and research and development processes and information as well as internal documents, such as laboratory notebooks).

14. Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of: (1) the nature of the materials or proceedings at issue; (2) the legitimate private or public interest which warrants the relief sought; (3) the clearly defined and serious injury that would result if the relief sought is not granted; and (4) why a less restrictive alternative to the relief sought is not available.

15. The information identified in the Declaration of Theodora McCormick and Appendix thereto satisfies the standards set forth in Local Civil Rule 5.3(c) and there is no less restrictive alternative to sealing the Materials.

**WHEREFORE**, the Court having found that the relief sought is warranted, and for good cause shown,

**IT IS ON THIS 6 DAY of December, 2018, ORDERED AS FOLLOWS:**

1. The Consolidated Motion to Seal is **GRANTED**.
2. The material identified in the Appendix to the Declaration of Theodora McCormick in Support of Motion to Seal contain Confidential and/or Highly Confidential Information and shall remain sealed.

**IT IS SO ORDERED.**

*s/Cathy Waldor*  
Hon. Cathy L. Waldor, U.S.M.J.